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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,429	08/02/2001	Lars Morch Groth	NN-6200.200 US	3993

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PATENT DEPARTMENT  
SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP  
FOUR TIMES SQUARE  
NEW YORK, NY 10036

EXAMINER

PICKETT, JOHN G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 08/26/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/921,429

Applicant(s)

GROTH, LARS MORCH

Examiner

Greg Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office action acknowledges the applicant's Amendment A, presented as Paper No. 7. Claims 11-18 are pending in the application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Specification***

3. The disclosure is objected to because of the following informalities: Page 8, line 25 cites "cover 6", page 9, line 1 cites "cover 6", and "cover 5is", applicant has denoted the cover as item 5 previously.

Appropriate correction is required.

### ***Claim Objections***

4. The objections to claims 2, 4, 6, and 7-10 are rendered moot by their cancellation.
5. Claim 11 is objected to because of the following informalities: Line 13, "extends" should be singular; line 15, "substantial" should be "substantially".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The applicant has canceled claims 5 and 6 rejected under 35 U.S.C. 112, second paragraph.

7. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is dependent on a cancelled claim.

***Claim Rejections - 35 USC § 102***

8. The applicant has cancelled claim 1 rejected under 35 U.S.C. 102(b).

***Claim Rejections - 35 USC § 103***

9. The applicant has cancelled claims 1-6 rejected under 35 U.S.C. 103(a).

10. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nguyen et al. (US 5,873,462) in view of Current (US 4,203,518).

Regarding claim 11, Nguyen et al discloses a needle magazine (10) with a cylinder-shaped base member (30) having a bottom surface (bottom of 30), an upper surface (32), a cylindrical wall surface (outside wall of 30), and spaced cavities (31) containing needle assemblies (100) and having a sterility barrier (150); a cover (20) having a first part (top surface of 20) and a slot (21). Nguyen et al meets all limitations claimed by the applicant except:

Nguyen et al does not disclose radial extending cavities, a cover with a second part parallel to the cylindrical surface or the slot provided on the second part of the cover.

Current discloses a cover (24) with a second part (28) parallel to a cylindrical surface (20) and a slot (34) provided on the second part (28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the magazine of Nguyen et al by rotating the vertical compartments to the horizontal position and providing the magazine with radial extending cavities and a cover as taught by Current in order to reduce the overall height of the container. Such a modification is deemed a mere rearrangement of parts, and it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 86 USPQ 70.

With the overall purpose of modification being height reduction, it would have been obvious to one of ordinary skill in the art to limit the height as much as possible. As such, it would have been obvious to limit the magazine height of Nguyen-Current to the width of the cavities (Nguyen et al, Figure 6); thereby creating a total magazine height that is insubstantially greater than the diameter of the needle assembly.

As to claims 12 and 13, the examiner assumes claim 12 to depend from claim 11. The magazine of Nguyen-Current provides a means for preventing one directional rotation of the cover in the form of ratchet assemblies (Nguyen et al, 33 and 25).

As to claims 14 and 15, the magazine of Nguyen-Current provides a means for preventing the cover from rotating more than 360 degrees in the form of first protrusion

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(Nguyen et al, 26) on cover (Nguyen et al, 20) and second protrusion (Nguyen et al, 36) on base member (Nguyen et al, 30).

Regarding claim 16, Nguyen et al discloses a tool (10) with a cylinder-shaped base member (30) having a bottom surface (bottom of 30), an upper surface (32), a cylindrical wall surface (outside wall of 30), and a plurality of elongated cavities (31) of circular cross section (as shown, Figures 2 and 6) having a means for gripping and securing a needle assembly against rotation (44) and sterility barrier (150); a cover (20) having a first part (top surface of 20) and a slot (21). Nguyen et al meets all limitations claimed by the applicant except:

Nguyen et al does not disclose radial extending cavities, a cover with a second part parallel to the cylindrical surface or the slot provided on the second part of the cover.

Current discloses a cover (24) with a second part (28) parallel to a cylindrical surface (20) and a slot (34) provided on the second part (28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the magazine of Nguyen et al by rotating the vertical compartments to the horizontal position and providing the magazine with radial extending cavities and a cover as taught by Current in order to reduce the overall height of the container. Such a modification is deemed a mere rearrangement of parts, and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

With the overall purpose of modification being height reduction, it would have been obvious to one of ordinary skill in the art to limit the height as much as possible.

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As such, it would have been obvious to limit the magazine height of Nguyen-Current to the width of the cavities (Nguyen et al, Figure 6); thereby creating a total magazine height that is insubstantially greater than the diameter of the needle assembly.

As to claim 17, the magazine of Nguyen-Current provides a means for preventing one directional rotation of the cover in the form of ratchet assemblies (Nguyen et al, 33 and 25).

As to claim 18, the magazine of Nguyen-Current provides a means for allowing each cavity to be accessed only once in the form of ratchet assemblies (Nguyen et al, 33 and 25) and rotational locking pins (Nguyen et al, 26 and 36).

### ***Response to Arguments***

11. Applicant's arguments filed June 10, 2003 have been fully considered but they are not persuasive.

12. In response to applicant's argument that Current is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Current is considered pertinent to the problem of compact storage of a needle magazine.

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13. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Nguyen et al is clearly the base reference, which is modified with the radial access taught by Current. Applicant's arguments as to the ability to modify Current with a sterility barrier and gripping means are irrelevant to the rejection presented.

14. In response to the applicant's arguments of unexpected results, the examiner has thoroughly considered the arguments in accordance with MPEP § 716.02(c) and 716.01(d) and finds the arguments not persuasive. Evidence of unexpected results must be weighed against evidence supporting *prima facie* obviousness in making a final determination of obviousness of the claimed invention. *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978). Although the record may establish evidence of secondary considerations which are indicia of nonobviousness, the record may also establish such a strong case of obviousness that the objective evidence of nonobviousness is not sufficient to outweigh the evidence of obviousness. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 769, 9 USPQ2d 1417, 1427 (Fed. Cir. 1988), cert. denied, 493 U.S. 814 (1989); *Richardson-Vicks, Inc., v. The Upjohn Co.*, 122 F.3d 1476, 1484, 44 USPQ2d 1181, 1187 (Fed. Cir. 1997) (showing of unexpected results and commercial success of claimed ibuprofen and pseudoephedrine combination in single tablet form, while



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supported by substantial evidence, held not to overcome strong *prima facie* case of obviousness). See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a detailed discussion of the proper roles of the examiner's *prima facie* case and applicant's rebuttal evidence in the final determination of obviousness.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Greg Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 8:30 AM to 5:00 PM.

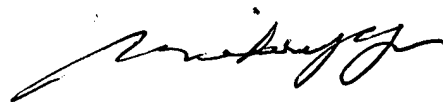
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Gregory Pickett  
Examiner  
August 12, 2003



Mickey Yu  
Supervisory Patent Examiner  
Group 3700